REMARKS

Applicants respectfully request reconsideration and withdrawal of the pending rejections for the reasons set forth herein below.

I. STATUS OF THE PENDING CLAIMS.

Claims 1, 4-5, 7, 9, and 11-23, 27-40 are pending in this Application. Claim 12-23 remain withdrawn. Claims 1, 4-5, 7-9 have been amended. Claims 27-40 are new. Claims 1, 4-5, 7, 9, 24-25 stand rejected.

Support for the new limitations can be found at pages 3, 6-7, 22-23, and 26-27. Specifically, "in vitro dissolution testing" is described at page 6, lines 25-29, page 12, lines 20-22, and page 30, lines 11-22; the recitation of compositions free of "an opiate antagonist" is described at page 3, lines 8-10; the recitation of "a hard gelatin capsule" is described at page 27, line 2; the recitation of "a plurality of microspheres" is described at page 26, lines 24-29; the recitation of microspheres particle sizes are described at page 22, lines 22-23; the recitation of immediate release microspheres is described at page 18, lines 26-29; the recitation of coating material is described at page 5, lines 1-5 and page 15, lines 1-2; the recitation of pharmacokinetic characteristics, such as T_{max} or duration of drug release is described at page 23, line 25 – page 24, line 6, and page 26 lines 21-23; and the recitation of the polymeric matrix is described at page 18, line 5 and page 5, lines 11-14; the recitation of polymers and waxes can be found at pages 12-14 of the Specification. Therefore, all newly added limitations have adequate support in the original Specification as filed and no new matter has been introduced.

II. REJECTION OF CLAIMS UNDER 35 U.S.C. § 112 FIRST PARAGRAPH IS IMPROPER.

The Examiner rejects claims 1, 4-5, 7, 9, 11 and 24-25 as allegedly containing the subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed has possession of the claimed invention.

Claim 1 has been amended for clarity. Claim 1 now recites "viscoelastic polymers," and the limitation directed to the dissolution rate requires the increase in the aqueous dissolution of said active water soluble compound be limited by less than about 15% of the total "pharmaceutically effective amount of the active water soluble compound in the composition in the first hour of *in vitro* dissolution testing." Support of such limitations can be found respectively at page 18, line 14 and at page 6, lines 26-28. Applicants believe that the presented amendments address the Examiner's concerns.

III. REJECTION OF CLAIMS UNDER 35 U.S.C. § 102(B) OVER PALERMO SHOULD BE WITHDRAWN IN VIEW OF THE CLAIM AMENDMENTS.

The independent claims expressly recite that the composition "does not include an antagonist to the water soluble compound capable of abuse." In contradistinction, Palermo's invention is premised on employing an opiate antagonist to impart the abuse resistance qualities of the composition. In other words, an opiate antagonist is necessary and required in Palermo's composition to counteract the opioid effects sought by the abusers, when Palermo's composition is tampered with to remove the content of its opioid agonists. *See* Abstract, also col. 9, ll.16-50. The abusive resistant feature of Palermo is caused by the opiate antagonists capability of counteracting, the opioid agonists effects, after Palermo's product has been tampered with.

Accordingly, contrary to Palermo's teachings, the present claims exclude the use of an antagonist to the active water soluble compound capable of abuse. Palermo's formulations, on the other hand, require the presences of a narcotic antagonist for its tamper resistant properties. Removal of said narcotic antagonist would destroy their proposed use. Therefore, any variation in Palermo's products that does not foresee the presence of a narcotic antagonist would have been a non-enabling disclosure for the purposes offered by Palermo.

The Examiner can not selectively disregard the essential element of the Palermo's inventive product, i.e., the opiate antagonist, to justify an anticipatory type rejection. If the prior art requires an essential element then, any variation of such product must also contain such element. Removal of such essential element would have deemed the prior art product inadequate and non-enabling for its intended use.

Moreover, Palermo can not, in any shape or form, be modified to render the present claims *prima facie* obvious, because unlike the present claims, the final product of Palermo must always contain a narcotic antagonist. The Court of Appeals for the Federal Circuit has made it clear that a suggestion in a prior art reference that would yield an inoperative device teaches away from the invention and cannot render the invention obvious. *See In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Again, since any modification of Palermo's formulation must ultimately contain a narcotic antagonist, removal of such component from Palermo's formulation would have made it inoperable and unsatisfactory for its intended purpose. For such reasons, any obviousness type rejection of the present claims over Palermo would also be improper.

CONCLUSION

In view of these remarks, applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, applicant welcomes the Examiner to call the undersigned at 609-844-3030.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,

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